

Utah

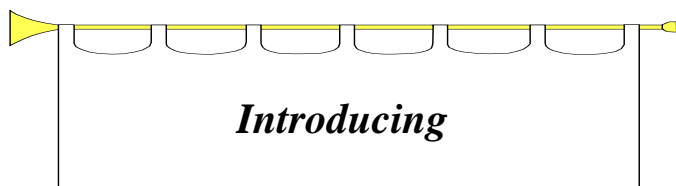
Department
of Health

Division of Epidemiology and Laboratory Services

Bureau of Laboratory Improvement

Web page: <http://health.utah.gov/els/labimp>

February 2003



1. Make sure suspicious isolates are pure cultures. Many presumptive VRSA are really MRSA mixed with VRE (vancomycin resistant enterococci) or *Lactobacillus*.

2. Test any isolate with a disk diffusion zone diameter of 14 mm or less with an approved MIC method (Microscan Walkaway/auto/touchscan system - conventional methods, Vitek, Etest, Pasco, Sensititre, broth dilution methods, or agar dilution).

3. For labs that don't perform MIC, screen *Staph aureus* isolates with commercial vancomycin screening agar (BHI agar containing 6 ug/ml vancomycin). Inoculate the agar with 10 uL of a 0.5 McFarland suspension. Incubate in ambient air (no CO₂) a full 24 hours. More than one colony = resistant isolate, 1 colony is a negative test.



NOTEWORTHY

👉 RAPID HIV TEST: The Food and Drug Administration (FDA) approved the OraQuick Rapid HIV-1 Antibody Test on November 7, 2002. The 20 minute antibody test is approved for point-of-care use to aid in diagnosing the presence of human immunodeficiency virus type 1 infection. The test was reclassified in January as CLIA waived. The patient sample is finger stick whole blood.

For more information check CDC's MMWR at www.cdc.gov/mmwr/PDF.wk/mm5146.PDF.

👉 COAGULATION COLLECTION TUBE CHANGES: Studies comparing newer low-volume (1.8 and 2.7 mL) plastic collection tubes with the 4.5 mL glass tube (gold standard) are confusing. Bias occurs with some instrument reagent combinations and the new tubes, so the BD study left them out! Some experts believe the head

👉 READY OR NOT, VRSA CAN BE CAUGHT: Michigan's Department of Community Health reported the isolation of a vancomycin-resistant *Staphylococcus aureus* (VRSA) the end of last year. Martha Boehme, MT(ASCP) in the Division of Infectious Diseases asked "Is your laboratory ready for VRSA?" She gave three suggestions to make sure you are.

Contents	
Introductions	1
Noteworthy	1
Feature: ULT	4
CLIA Bits	5
P. T.	7
Safety Tips	7
Continuing Education	8

space in the new tubes is the problem. If so, there are newer tubes that are actually a tube within a tube so there is minimal headspace. Each laboratory is encouraged to perform their own study when changing any blood collection tube. That way you can discover problems with your exact tube-instrument-reagent combination. To read the entire coagulation article check the October, 2002 issue of CAP Today for "Quick on the draw – coagulation tube response" by Vida Foubister.

☞ **NEW CERVICAL CANCER**

SCREENING GUIDELINES: The American Cancer Society published new guidelines for how often women should have PAP smears.

Begin screening at age 21 or 3 years after becoming sexually active

Have a regular PAP test yearly (every 2 years if a liquid based screen is used)

After age 30, women with 3 negative consecutive annual screens may have a PAP every 2 or 3 years (unless the clinician feels they are high risk)

After age 70, women with 3 negative tests and no abnormal tests in the past 10 years may discontinue testing

After a total hysterectomy (cervix was removed) there is no need for screening unless the surgery was for cervical cancer or precancer treatment.

For the full report go to the website – <http://caonline.amcancersoc.org/cgi/content/full/52/6/375>.

☞ **DETECTING PATIENTS IN NEED OF**

RENAL DIALYSIS: Sharon Ehrmeyer, Ph.D., MT(ASCP) wrote an article in the January 2003 issue of MLO on using a urinalysis creatinine ratio to improve the detection of kidney disease over using only dipstick albumin and protein results. She states the latest National Kidney Foundation guidelines recommend monitoring proteinuria in patients at risk for kidney disease, such as diabetics. If a qualitative test is positive, a quantitative protein, or albumin-to-creatinine ratio should be done within 3 months.

"New routine urinalysis reagent strips are now available that measure both the total protein and albumin and allow for the determination of the

creatinine ratio. . . While these routine reagent strips are not quantitative, the semiquantitative results are usually all that is required for clinical decision making. If quantitation is required, there are now a number of easy-to-use test systems available for rapid quantitation of either protein – (or albumin-) to the urine creatinine level."

The new Bayer Multistix PRO and the Clinitek Microalbumin Reagent Strips for urinalysis contain these ratio pads. They are to be used on random urine specimens, not 24 hour collections.

☞ **PSA TESTING = SCREENING OR**

MONITORING?: Medicare began reimbursing PSA tests to screen for prostate cancer in 2000. There are many different PSA tests available. Make certain the one you choose is FDA approved for the purpose you are using it. Some manufacturers are permitted to claim that their test is useful only for monitoring prostate cancer patients. Some caution against using their test for cancer screening.

Be aware that the fixed cutoff value (4.0 ng/mL) many of us memorized for PSA screening was established some time ago using different test methods. While easy to remember, the specificity of that number will decline with the patient's age. In general, as a man ages, his prostate enlarges and PSA values increase.

The guidelines for PSA testing can be found at the American Urological Association website: www.cancernetwork.com/journals/oncology/o0002e.htm.

☞ **CULTURING THE ENVIRONMENT**

FOR *Bacillus anthracis*: The following is a synopsis of an article from CDC's Emerging Infectious Diseases Vol. 8, No. 10, October 2002 entitled "Environmental Sampling for Spores of *Bacillus anthracis*".

"On November 11, 2001, following the bioterrorism-related anthrax attacks, the U.S. Postal Service collected samples at the Southern Connecticut Processing and Distribution Center; all samples were negative for *Bacillus anthracis*. After a patient in Connecticut died from inhalational

anthrax on November 19, the center was sampled again on November 21 and 25 by using dry and wet swabs. All samples were again negative for *B. anthracis*. On November 28, guided by information from epidemiologic investigation, we sampled the site extensively with wet wipes and surface vacuum sock samples (using HEPA vacuum). Of 212 samples, 6 (3%) were positive, including one from a highly contaminated sorter. Subsequently *B. anthracis* was also detected in mail-sorting bins used for the patient's carrier route. These results suggest cross-contaminated mail as a possible source of anthrax for the inhalational anthrax patient in Connecticut. In future such investigations, extensive sampling guided by epidemiologic data is imperative."

I noted 3 important points in this article. You must know **WHERE** to collect samples by knowing the work flow. You must know **HOW** to collect samples (dry and wet swabs were repeatedly negative). You must have the proper **LAB PROCEDURES** for screening environmental samples. Bottom line = call your state lab for instructions when someone wants you to check an environmental sample for anthrax.

✎ **D-DIMER, ONE NAME – TWO TESTS:**

The November, 2002 MLO and the January, 2003 CAP Today featured the value and problems with D-dimer testing. Newer D-dimer quantitative assays can help diagnosis deep venous thrombosis (VTE) or pulmonary embolism, but the traditional latex agglutination D-dimer can help diagnosis disseminated intravascular coagulation (DIC).

D-dimer is a heterogeneous group of molecules. The lab should select the test – and name the assay to help clinicians know exactly what the test can do.

Richard A Marlar, Ph.D. summarized:

D-dimer should be used with caution for hospitalized patients. Many disease processes and invasive procedures can elevate D-dimer levels without any VTE.

D-dimer should not be used for patients on anticoagulant therapy (heparin or warfarin).

Since the range of detection necessary for the two assays is significantly different, we recommend that

the lab provide two assays (quantitative and qualitative) and offer them as different tests for clinician ordering. We use "D-dimer (Thrombosis)" to rule out VTE since it is most useful when negative; and "D-dimer (DIC)" for the latex test.

Since the International Society on Thrombosis and Haemostasis subcommittee have not been able to standardize D-dimer assays during the past ten years, all authors in these articles recommend each lab establish their own cut off value. Be sure you know which test you are offering and its limitations.

✎ **CONTAMINATED PLATELETS:** Anne Paxton summarized expert opinions on this topic in the December 2002 issue of CAP Today.

Dr. Brecher estimates that one patient a day develops life-threatening bacterial sepsis from contaminated platelets in the USA.

Jim MacPherson (chief executive officer of America's Blood Centers) says "The number of contamination-related transfusion reactions has been steady for 20 years. What *is* new is that deaths and infections from other types of viruses are so low that bacteria now stands out." Platelets are more susceptible to bacterial growth because they are not refrigerated. Studies last year show random donor platelets carry about 5 times the risk of apheresis platelets for post-transfusion sepsis and death.

FDA reports show platelet related deaths from the following bacterial contaminants:

<i>Staphylococcus aureus</i>	17%
<i>Klebsiella pneumoniae</i>	17%
<i>Serratia marcescens</i>	16%
coagulase negative Staph	10%
streptococcus	8%
salmonella	8%
enterobacter	6%
<i>E. coli</i>	6%
<i>Pseudomonas aeruginosa</i>	6%
<i>Bacillus cereus</i>	6%

It seems visually inspecting platelets before transfusing does not catch the 1,000 to 4,000

contaminated units. What can you do? There are test systems advertised (Pall Corp – BDS filter and BioMerieux – BacT/Alert) to detect bacterial growth. But maybe the best deterrent comes during collection. As 2/3 of the contamination occurs by introducing skin bacteria during venipuncture, the process to divert the first 30 or 40 mL of blood for testing purposes and using the later blood for the platelet packs can reduce contamination. Better donor screening to pick up persons with sub-clinical infection may help eliminate some of the remaining contaminants.

☞ **LIPEMIA INTERFERES WITH COAGULATION TESTS:** Obviously a high concentration of lipid globules in the blood interfere with any instrument that measures prothrombin and partial prothrombin time by light detection or scatter. Lipemia may artificially lengthen clotting times in optical clot detection methods.

Turbidimetric and nephelometric methods are affected by lipemia. Mechanical and electromechanical methods are not. NCCLS recommends the later two methods for coagulation testing on lipemic specimens.

You can avoid excess lipids in the sample by having the patient fast 12 hours before blood collection.

FROM THE PATIENT'S CHART

"Patient has left white blood cells at another hospital."

★ Feature: ★

UNESTABLISHED LABORATORY TESTS (ULT)

The Utah CLIA surveyors serve on a national committee to address Federal regulation of non-traditional laboratory tests that fall under the CLIA '88 definition. According to 42 CFR 493.2 a laboratory (requiring proper certification by CMS or its agent) "means a facility for the biological, microbiological, serological, chemical, immun-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories."

Some examples of ULT identified by the committee are Live Blood Cell Analysis, Bio-terrain Analysis, Metabolic Intolerance or Cytotoxic Test, and Herbal Crystallization.

The committee is charged by the Office of the Inspector General (OIG) to:

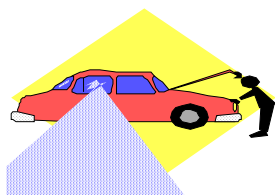
- require labs to disclose ULT on their CLIA application;
- seek new administrative authorities to permit CMS to take specific actions when a lab fails to enroll in CLIA;
- improve test verification reviews by standardizing the requirements and by training CLIA surveyors;
- use CMS internet site and other means to provide public information on ULT;

(and two other items not within our scope or capabilities that will be given to other agencies).

Several labs performing ULT in the USA are CLIA certified. Three facilities in Utah had CLIA certification but were unable to meet all the requirements for high complexity testing. Other facilities may have CLIA certification (usually a certificate of waiver), but the CLIA agencies are unaware they perform ULT.

If you are aware of facilities performing ULT in Utah, please contact the CLIA agency at 801-584-8471. The agency will send the facility a letter requesting they comply with CLIA regulations. They will be given information on what type of method validation is needed, personnel qualifications and quality assurance needs.

The committee is planning a meeting with all stake holders and interested parties within a year. The participants will focus on informing the public and methods of enforcement for facilities that refuse to comply with CLIA regulations.



CLIA BITS:

ADDITIONAL WAIVED TESTS:

- ° Polymer Technology Systems Bioscanner Plus, Cardiochek Analyzer, and Cardiochek PA Analyzer for cholesterol, HDL cholesterol and triglyceride
- ° Lifescan Harmony INR Monitoring System for prothrombin time
- ° Maritech, Inc. NMP22 BladderCheck Test for bladder tumor associated antigen
- ° Home Diagnostics ShopRite Blood Glucose System IQ and Blood Glucose System
- ° Metrika A1c Now for glycosylated hemoglobin

° ARKRAY PocketChem Action Sticks 10TA and ThermoBiostar PocketChem UA urine dipsticks

° Hypoguard Diascreen 50 Urine Chemistry Analyzer for urine dipsticks

° Germaine Laboratories StrepAim Rapid Dipstick Test for group A Strep

° Henry Schein Inc, One Step+ Strep A Test for group A Strep

° DE Healthcare Products TruView Strep A Test for group A Strep

° OraSure Technologies OraQuick Rapid HIV-1 Antibody Test for HIV antibodies

MORE HIPAA

On April 14, HIPAA privacy regulations take effect. Think about your lab's:

Verbal Communication including phone calls, pagers, voice mail and answering machines. In coming and out going calls. Confirm the identity of the person on the other end of the line. You could have caller ID or set up some pass word or client number identification system.

Courier – seal the envelopes containing results for delivery and have receiving facility sign they were received sealed. Instruct your couriers on lab privacy policies.

Mail – establish a process to confirm the right results are going to the correct client. Have a process to detect and correct process failures.

Electronic hard copy (fax, remote teleprinter) confirm the fax/printer number before sending private information. How do you label results so the facility knows who should have the results? Determine where ownership for the results ends.

For technical assistance call 1-866-627-7748 or go to www.hhs.gov/ocr/hippa

2003 HCPCS

14 CPT codes for CLIA tests were discontinued.

2 PPM codes were inadvertently discontinued but will be reinstated.

4 codes require an LC code but the information was left off the Medicare code book (0010T LC 220, 0026T LC 310, 0041T LC 110, 86146 LC 220)

There are 14 new codes. Code 0040T shows a LC code when it does not need one.

Contact your Medicare carrier for a list of the changes and information on when the updated listing will be available.

CLIA Final Regulation Published

Federal Register, Vol. 68, No. 16 published January 24, 2003 (and you thought “not in my lifetime”!)

The changes in the rule will be minimal for Utah labs. Most changes are a decrease in quality control frequency in bacteriology and hematology. Some “changes” were already required as Director Duties by Utah surveyors.

The regulations are online at www.phppo.cdc.gov/clia/pdf/CMS-2226-F.pdf

Here is a summary of the changes that are effective April 24, 2003:

Age or date of birth required on all test requisitions.

Specimen source must be on the specimen label if the information is necessary for testing.

Automated CBC tests = minimum 2 levels of control each day of testing (more if required by instrument manufacturer)

Molecular biology – QC must detect product inhibition

Electrophoresis – 1 level of control must contain the substance being detected

Microbiology – control each batch, lot number or shipment of stain, reagents (catalase, coagulase, oxidase, disks – bacitracin, optochin. ONPG, X, V, X & V), antisera and identification systems made or received with a positive (graded reactivity if applicable) and negative control before use. **Beta-lactamase (other than cefinase) and DNA probes must still be checked each day of use with a positive and negative control.**

Mycobacteriology – check all reagents and AFB stains each day of use with a positive and negative organism. Check fluorochrome stains each time of use with a positive and negative organism.

Mycology – check each batch, lot number and shipment of lactophenol cotton blue, reagents, disks, stains, antisera and identification systems for positive and negative reactivity when prepared or opened for use.

Immunology (including syphilis testing) – 2 levels of control each day of testing, not each run.

Virology – incubate a negative tissue with cell cultures.

Calibration verification must have 6 points (may use 3 points twice).

Rotate quality control performance among all testing personnel.

“Each laboratory that introduces an unmodified, FDA-cleared or approved test system must, before reporting patient test results, demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the specified performance characteristics.” (For kits, instruments, test systems new to the lab beginning April 24, 2003.)

Keep preliminary, final and amended test reports 2 years.

Add a confidentiality standard (HIPPA) to your quality assurance plan.
Document the date and time a specimen is received in your facility for testing.

You can use a calibrator for quality control purposes only if it is from a different lot number or manufacturer than the one used to calibrate your test run.

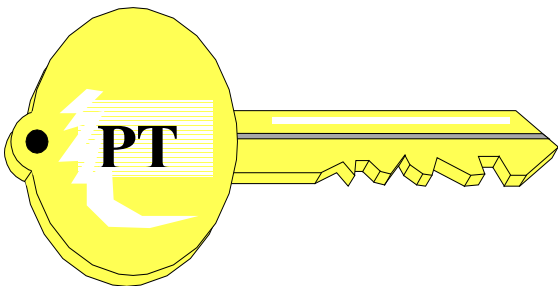
As of February 24, 2003 all individuals with a doctoral degree (not already serving as a high complexity lab director) must have board certification in a specialty for which they wish to be qualified to direct a high complexity laboratory.

“real” cause of the problem since the first corrective action applied did not stop poor performance. Avoid 6 months of not testing and avoid the cost of extra proficiency test samples. A proficiency test failure, for whatever reason, points to a problem in your test system. We hear many excuses that employees didn’t know what PT was and what to do with it. This is a problem in the pre-analytic part of lab testing, or training, or lack of a written procedure. It is a problem that affects testing and needs to be corrected.

The number of proficiency test failures in Utah increases slightly each year. Avoid the headache. Investigate that first failure more deeply to discover the “root cause” of the problem so your fix will prevent future failures.

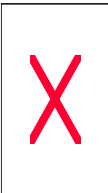
Equals

“1 millionth of a mouthwash: 1 microscope”



This past year, several Utah laboratories lost the approval for a certain test or group of tests because of repeated proficiency test failure. Utah usually gives a laboratory an extra chance to fix a testing problem before imposing sanctions. The CLIA regulations allow a sanction, such as 6 month testing suspension and cessation of Medicare / Medicaid payments for 2 of 3 event failures.

We find some laboratories fail to pay attention to the first failure. By the time there is a second failure, the laboratory should be looking for the



Safety Tips

CONTAMINATED BLOOD SCARE

In February, the FDA issued recommendations for additional blood inspection protocols as a precautionary measure while investigation of the white particulate matter contaminating blood products continues. Most of the contamination reports are associated with a blood bag sampling port manufactured by Baxter Healthcare Corp. The majority of cases are coming from Red Cross blood centers in Tennessee and Georgia. The exact nature of the particulate matter is under investigation. Preliminary results reported to the FDA suggest that some particles identified represent normal platelet clumping. CDC has found no evidence of infectious agent contamination to date.

OSHA SAFETY AUDIT

COLA recommends you perform the following self audit to determine your compliance with OSHA regulations:

Are Universal Precautions always observed?
Has the Bloodborne Pathogen Exposure Control
Plan been reviewed within the past year and
updated if necessary?

Have your hazard communication and Chemical
Hygiene plans been reviewed within the past year
and updated if necessary?

Have fire extinguisher and eyewash station checks
been performed and documented?

Have shock hazards been evaluated and preventive
steps taken?

Have all new employees at risk for exposure to
bloodborne pathogens been offered Hepatitis B
vaccination within 10 days of hire?

Have all employees received annual OSHA safety
training?

Are you using the safest possible sharps?

If you can answer yes to these questions, you will
probably pass a surprise OSHA inspection.

SPECIMEN TRANSPORT REGULATIONS

Both DOT (Department of Transportation) and
IATA (International Air Transport Association)
made changes in their respective shipping
regulations for 2003. DOT (effective 2/14/03) is
regulating the shipment of diagnostic specimens for
the first time. There are requirements for packaging
and the package must be marked "Diagnostic
Specimen". IATA (effective 1/1/03) has assigned a
UN number for diagnostic specimens: "UN3373
Diagnostic Specimen".

Check their respective websites for complete
information. Both agencies can impose substantial
fines for non-compliance.

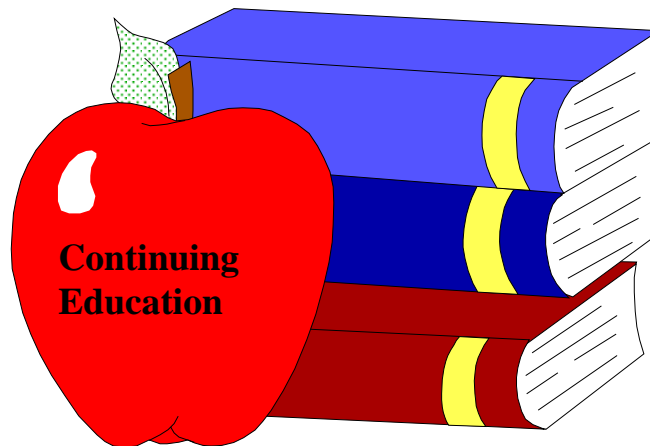
UTAH PATIENT SAFETY DATA PUBLISHED

A first year summary of Utah's patient safety
initiative was released 12/20/02. The report was
compiled by the Utah Department of Health
(UDOH), Utah Hospitals and Health Systems
Association, and HealthInsight. The UDOH's
patient safety rules took effect October 1, 2001 and
require hospitals and outpatient surgical centers to
report adverse medical and drug events. The
facilities must have programs to improve patient
safety. Utah is one of 20 states that require medical
error reporting.

For additional information, contact Wu Xu, UDOH
Office of Health Care Statistics at 801-538-7072.

IF YOU SEE SOMEONE WITHOUT A SMILE,
GIVE THEM ONE OF YOURS.

Author unknown



1. UPH Lab - BLI

Lending Library Additions:

U-80: *A New Era in Newborn Screening, Saving
Lives, Improving Outcomes*, CDC, 1.75 hour video,
four case histories, tracks specimen from collection

to patient follow-up, discussion of what new testing is becoming available.

U-81: *SpectroPrep*, CEM, 10 minute video ad for Applied Microwave Technology in environmental chemical sample preparation.

U-82: *Lab Technician Training Program*, 15 minute video by NUS. An ad for a 27 unit video presentation. Each unit is a 30 minute training session covering topics from atomic absorption to safety issues. Resource for training environmental chemists.

2. NLTN LENDING LIBRARY

CD Rom: *Antimicrobial Susceptibility Testing*, CDC, 2002.

CDC has prepared a free CD that can be used to train clinical microbiologists on Antimicrobial Susceptibility Testing. It is a self-study course that comes with 7 CEU or CME hours. The course reviews general information on antibiotic resistance mechanisms, testing methods, and more detailed information on Gram-positive and Gram-negative organisms. You can order your own copy at www.phppo.cdc.gov/dls/master/default.asp

3. NCCLS

GP2-A4: *Clinical Laboratory Technical Procedure Manuals*

GP26-A2: *Application of a Quality System Model to Laboratory Services*

M2-A8: *Performance Standards for Antimicrobial Disk Susceptibility Tests*

M7-A6: *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically*

M11-A5: *Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria*

M100-S13 (M11): *Anaerobic Dilution Supplemental Tables*

4. CELEBRATE!

National Medical Laboratory Week –
April 20-26, 2003

LABORATORY PROFESSIONALS:
EXCEPTIONAL PEOPLE – EXCEPTIONAL
WORK

Contact ASCP for a planning guide. Let the public know how much they need laboratory professionals behind the scene.

**1999 British GCSE exam results from
16 year olds:**

Q: What does “varicose” mean?

A: Nearby.